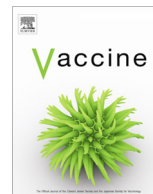




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Commentary

The scourge of vaccine falsification

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ABSTRACT

Fake vaccines trafficking is a recent but growing phenomenon, which represents a severe threat to public health. During the Covid-19 pandemic, anti-Covid vaccines have been a prime target for traffickers, but all types of vaccines are falsified by profit-hungry criminals.

The consequences of falsification on global health are serious: decline in vaccination coverage, loss of control of epidemics which will claim yet more victims, and resurgence of diseases that were under control. Fake vaccines also fuel the mistrust of populations towards science and authorities.

In order to tackle this scourge, a general and coordinated mobilization of all actors concerned is urgently needed: health professionals, political decision-makers, police and customs forces, judges and prosecutors, without forgetting the crucial awareness-raising of public opinion.

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1. Introduction

At least two to three million lives are saved in the world each year thanks to vaccination [1]: one of the greatest successes in medicine.

A century after the first vaccination against smallpox in 1796, based on the brilliant observation of the English physician Edward Jenner, Louis Pasteur defined the role of microorganisms in the spread of infectious diseases and demonstrated the scientific mechanism behind vaccination. The great saga of vaccine prevention was launched.

Successes obtained in the rich countries are replicated in the poorest countries, through the Expanded Programme on Immunization established in 1974 [2]. In 2020, the use of messenger RNA (mRNA) vaccines against Covid-19, developed in record timing (after twenty years of research on the promising mRNA technology), opened new perspectives and generated new hopes. But vaccination is under attack, not only by “antivax” groups but also by criminals who falsify vaccines and medicines for their profit, disregarding the risks to people’s health. Far from being an isolated phenomenon, fake vaccines trafficking is a growing threat that strikes the poorest countries most heavily but now extends to every continent and represents a severe danger to global health. Robust scientific data are still lacking on this scourge and large-

scale studies should be conducted to better assess it. But many examples already show the magnitude of the threat and the need to tackle it without delay.

2. History of fake vaccines

The first case of falsification of a vaccine was documented in 1995. While a new epidemic of group A meningococcal cerebrospinal meningitis was spreading in Niger, an emergency vaccination campaign was put together to break the epidemic curve. As no evidence for control of the epidemic was observed [3] coupled with the doubtful appearance of the vaccines [4], *Médecins Sans Frontières* and health authorities of Niger alerted the supposed manufacturer. After checking batch numbers and performing laboratory analysis the suspicion was confirmed: the vaccines were fake, containing no active ingredient! 88 000 doses of meningococcal vaccine originating from Nigeria were concerned, of which around 60 000 had already been injected [5].

Still today, efforts against meningococcal disease are constantly sabotaged by traffickers: falsified vaccines were identified in West Africa, especially in Niger, in 2015 [6], 2017 [7] and 2019 [8].

While an epidemic of breakthrough infections permitted the falsification of vaccines to be revealed, it is likely that similar fake vaccines were traded previously. Indeed, in large scale “preventive” vaccination campaigns against diseases other than meningitis, a fake vaccine is much more difficult to identify: In countries that lack pharmacovigilance systems or follow-up of the patients

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vaccinated, if there are no severe adverse effect to expose the fraud, it is difficult to spot fake vaccines.

Health consequences of fraudulent vaccines are serious at both the individual and the collective levels: besides the risks of toxicity and microbial contamination, failure to prevent the disease targeted by the vaccine could lead to uncontrolled spread of an epidemic and multiplication of victims. Except for a mass reaction incident, detecting the falsification could take years making it impossible to precisely quantify the damage and delaying awareness of this scourge.

In 2016, Indonesia discovered that a criminal organization had been smuggling fake vaccines into the country for thirteen years [9]: Combined pediatric vaccines against diphtheria, tetanus, poliomyelitis, whooping cough and *Haemophilus influenzae type b* infections, as well as vaccines against hepatitis B and BCG vaccine against tuberculosis had been falsified and distributed in nine regions and nearly forty hospitals and clinics across the country [10]. Unable to assess how many children had received these fake vaccines, the Indonesian government urgently launched a massive re-vaccination campaign [11] and undertook a radical overhaul of the medicine agency which despite being alerted three years earlier about the existence of such vaccine trafficking, had not given it any attention [12].

In addition to health consequences, fake vaccines deeply undermine public confidence in scientific medicine and authorities.

All vaccines can be falsified. Recently, for example:

- In Bangladesh in 2016, falsification of the vaccine against yellow fever [13] was identified through errors on the packaging including a fake expiration date.
- In Uganda in 2018, falsification of vaccines against hepatitis B [14], was spotted during a routine post-market surveillance, because of label inconsistencies. Laboratory investigations showed no harmful ingredient but significantly lower antigen potency than the authentic vaccine.
- In Bangladesh again, in 2019, 8 000 packs of fake oral cholera vaccine were distributed [15], packages displayed a fake batch number and a non-existent combination of manufacturers.
- In the Philippines in 2019, traffickers exploited the shortage of rabies vaccine to distribute batches of falsified rabies vaccines and antiserum [16].

Veterinary vaccines are concerned too: a falsified rabies vaccine was identified in Poland in 2017 [17] and fake veterinary vaccines trafficking is probably widespread in Africa.

3. And now the anti-Covid vaccines

Since early 2020, scientific research has made it possible to conceive, develop, produce and put on the market in record time safe and effective vaccines against Covid-19, giving the hope of controlling the epidemic in the coming months. But criminals were ready-to-react, seeing in the launch of this global vaccination campaign an opportunity for lucrative trafficking [18]:

- In lower-income countries, taking advantage of the difficult access to these high-quality Covid vaccines and the deficiencies of pharmaceutical distribution, traffickers disseminate fake vaccines in parallel channels such as private clinics, “natural health” centers, and private companies. In Mexico [19] and Ecuador, among others, thousands of people received one or more injections of these falsified vaccines [20]. An illegal vaccination center has also been closed in India and falsified anti-Covid vaccines were identified in Burma, China, Iran and Uganda [21].

- In other countries, exploiting supply difficulties and confusion generated by excessive, alarmist, often negative or doubtful communication, traffickers trade fake vaccines on the hidden side of the Internet, the dark web [22], at up to 1 000 dollars per dose [23].

In high income countries, extremely rigorous market authorizations and vaccine control procedures [24] (internal controls by the industrial company at every stage of the manufacturing process and external controls by the medicine agency that delivers batch release certificates) are a guarantee of vaccine quality and safety. However, in lower- and middle-income countries and in particular in Africa, there is no such protection. Pharmaceutical circuits are much more vulnerable, especially in emergency situations, and constitute a privileged target for traffickers. Furthermore, in many countries, rampant and massive corruption at all levels of the society fuels falsification and trafficking of medicines and vaccines and allows them to flourish.

4. What to do?

Vaccination is under attack on every continent: slandered and taken to task by sectarian and conspiracy groups, questioned by a population which has not known or has forgotten the seriousness of infectious diseases, usurped by crooks who put in danger the health of populations. In face of this growing and deadly threat, there is an urgent need for a general mobilization.

4.1. In developing countries

Pharmaceutical circuits must be strengthened by giving regulatory agencies the human, financial and technical resources as well as the political support they need to carry out their mission of monitoring and controlling medical products, in particular vaccines.

In Africa, the PanAfrican Veterinary Vaccine Center (PANVAC) is recognized as a center of reference for quality control of veterinary vaccines by the Food and Agriculture Organization of the United Nations [25,26].

However, with regard to human vaccines, only one laboratory, in South Africa, has the capacity to control vaccines and is prequalified by the World Health Organization for such an expertise [27].

4.2. In developed countries

Civil society must be made aware of the risks of falsified vaccines and urged to refuse any proposal to furnish vaccines coming from the Web (“vaccines, like medicines, are not just common goods!”).

4.3. Everywhere

A strong commitment from health authorities together with the police and customs forces, judges and prosecutors must be obtained and those authorities provided with the means to faster identify fraud and to prosecute the perpetrators by criminalizing the acts thanks to the Medicrime Convention of the Council of Europe [28], the only international criminal-law instrument countering the trafficking of falsified medical products.

The fight must also focus on public opinion, through constant information campaigns and a rigorous struggle against disinformation. Awareness must be raised among health professionals on the front line about this trafficking and its disastrous consequences.

5. Conclusion

Humanity is once again relying on vaccination. Falsification of vaccines is a significant problem in developing countries and must be attacked by all possible means, particularly during the Covid-19 pandemic. The plague of falsified vaccines will not disappear with an end to the pandemic and will exist unless authorities throughout the world take vigorous steps to counter it.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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